

Food and Drug Administration, HHS

§ 522.960b

intramuscular injection of from 1 to 2 milliliters of the drug to each animal at any time between 5 to 28 days of age.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 38938, Oct. 2, 1984; 50 FR 23298, June 3, 1985; 50 FR 25216, June 18, 1985; 51 FR 14989, Apr. 22, 1986; 51 FR 18314, May 19, 1986]

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) of florfenicol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 20 mg per kilogram (/kg) of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(A) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(B) [Reserved]

(ii) *Amount.* 40 mg/kg body weight as a single subcutaneous injection.

(A) *Indications for use.* As in paragraph (d)(1)(i)(A) of this section; for control of respiratory disease in cattle at high risk of developing BRD associated with *M. (Pasteurella) haemolytica*, *P. multocida*, and *H. somnus*.

(B) [Reserved]

(iii) *Limitations.* Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 42383, Aug. 15, 1996, as amended at 63 FR 26981, May 15, 1998; 63 FR 41191, Aug. 3, 1998; 64 FR 5596, Feb. 4, 1999; 64 FR 9435, Feb. 26, 1999; 67 FR 6866, Feb. 14, 2002]

§ 522.960 Flumethasone implantation or injectable dosage forms.

§ 522.960a Flumethasone suspension.

(a) *Chemical name.* 6 α ,9 α -Difluoro-11 β ,17,21 - trihydroxy - 16 α - methylpregna - 1,4 - diene - 3,20 - dione.

(b) *Specifications.* Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of flumethasone, 20 milligrams of propylene glycol, 9 milligrams of benzyl alcohol (as preservative), 8 milligrams of sodium chloride, 0.02 milligram of polysorbate-80, 0.1 milligram of citric acid, and water for injection q.s.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpalitis, and osselets.

(2) The drug is administered intraarticularly at a dosage level of 6 to 10 milligrams per injection. The dosage level is dependent upon the size of the involved synovial structure and the degree of severity of the condition under treatment. The dosage is limited to a single injection per week in any one synovial structure.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally and parenterally to animals during the last trimester of pregnancy may induce the first stage of parturition and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The drug is not to be used in horses intended for slaughter for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

§ 522.960b Flumethasone acetate injection.

(a) *Chemical name.* 6- α ,9- α -difluoro - 16 - α - methylprednisolone 21-acetate.

(b) *Specifications.* Flumethasone injection is sterile and contains per cubic